REMARKS

Status of Claims

Claims 1 – 73 were original in the application. Claims 1 – 34, 41 – 45, 48, and 57 – 73 have been withdrawn and cancelled without prejudice. Claims 36 and 39 have been cancelled and the subject matter included in claims on which they depended. Claim 35, 37, 49, 54, 55, and 56 have been currently amended. Claims 35, 37, 38, 40, 46, 47, and 49 – 56 as amended or originally filed are submitted for examination on the merits.

Rejection Pursuant to 35 USC 102(e)

Claims 35 – 39 and 49 – 56 were rejected as being anticipated by Eggers US Patent 6,557,559.

The Examiner cited Eggers as disclosing the claimed invention as follows. The Examiner contended that in numerous embodiments (see figures 1,2, 16, 16a, 17) devices for shaping/recontouring cartilage (col. 5:60-67; col. 7:55-60; col. 12:15-20) for use in methods (claims 33, 46, 69) including pressuring/creating stress/mechanically applying force in target tissue with a probe and applying electrical energy to the target tissue (see col. 6:61-67). Eggers also discloses arrayed electrodes/paired conductive elements (58), a power source (28), voltage source (98), a controller including temperature feedback control (28), selector (30 - changes applied voltage level), constant current flow (col. 9:20-25) and control (duration, level, intervals) of the voltage pulses (col. 8:19-33).

Eggers is acknowledged as specifically directed to cutting, shaping or ablation of fibrocartilage and articular cartilage during arthroscopic or endoscopic procedures. The electrode arrays are formed at the distal tip of the electrosurgical probe shaft, such as in planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures.

With regard to claim 35 the Examiner contends that Eggers discloses an apparatus of electroforming tissue comprising: means for creating stress in the tissue (see col. 6:61-67) to temporally define and maintain a predetermined shape of the tissue (the physical presence of the probe may temporally physically displace the tissue while the probe is adjacent the tissue); and means for causing a current to flow in the tissue (see col. 6:61-67; power source 28, voltage source 98, electrodes 58) while the created stress is present to permanently change (changes resulting from current application) shape of the tissue or material parameters of the tissue without necrosis or ablation (col. 5:60-67; col. 7:55-60; col. 12:15-20). Continuing with claim 36, the Examiner contends that the Eggers discloses means for causing a direct current (col. 9:20-25) of a predetermined polarity (col. 1:30-35) to flow (power source 28, voltage source 98, electrodes 58) in the tissue to mediate the tissue.

Claim 36 has been incorporated into claim 35. Again the Examiner has not cited any electroforming technique against the pending claims. Eggers is distinguished on the ground that if fails to disclose electroforming. Electroforming and dielectric heating by RF are completely distinct bioeffects in tissue, and specifically cartilage. The Examiner contends that a DC current is disclosed at col. 9:20 - 25, but what Eggers actually discloses is a **constant RF current**. Col. 8:19-33 is cited by the Examiner for a DC pulse train, but again Eggers disclosed in fact **a pulse train of RF current**. The

"DC power source 28" referenced by the Examiner is actually called a **high frequency power** *supply* 28 by Eggers. Claim 35 as amended, the sole independent claim, calls for a means for causing a **direct current** of a predetermined polarity to flow in the tissue to mediate the tissue while the created stress is present to permanently change shape of the tissue or material parameters of the tissue without necrosis or ablation. RF current in any form does not have a polarity but is by definition a high frequency alternating current, and is not a direct current.

It cannot be sustained that each and every element of claim 35 as amended is disclosed by Eggers.

With respect to claim 37 the Examiner contends that Eggers discloses a means for creating stress in the tissue comprises means for mechanically applying force (see col. 6:66-67) to the tissue to create external stresses applied to the tissue to temporally define and maintain a predetermined shape (col. 5:60-67; col. 7:55-60; col. 12:15-20) of the tissue.. The means for creating stress in the tissue comprises means for changing material parameters (see col. 6:61-67) of the tissue to create internal stresses in the tissue to permanently change its shape (col. 5:60-67; col. 7:55-60; col. 12:15-20) to the predetermined shape.

Eggers discloses in the various cited paragraphs a probe shown in Figs. 2 and 3 which are alleged to "recontour" or "shape" the tissue. There is no specific disclosure how the probe is to bring about any particular recontouring or shaping, other than by means of "pressure against the target tissue using the probe itself." However, the probe is shown in Fig. 3 simply as a planar array of electrodes 58. None of the various

embodiments of Eggers shows anything which could fairly be characterized as a mold.

Paragraphs [0076] and [0077] of the application disclose:

> [0076] In a surgical context as shown in FIG. 10 an instrument can be devised in which the two electrodes are brought to bear on the tissue site either in the form of pressure electrodes or penetrating electrodes or both. The electrode pair 68 may, for example, be mounted on and electrically isolated on a pair of tongs 66 coupled to a current or voltage source 16 and comprise a **mold**. The surgeon then brings the instrument 66 into contact with at least one of the **molded surfaces** of the tissue to be reshaped, creates the stress, and applies an effective voltage for effective time to obtain the **molded shape** desired. The electrodes 68 may be subdivided into multiple pieces so that there is an array of small plate electrodes or a needle array as described above. (emphasis added)
>
> [0077] For example, where only one surface of the cartilage or tissue is accessible, a **molded electrode surface** is brought to bear against the accessible tissue surface to provide pressure or stress in the tissue, namely to indent the surface, and one or more needles are inserted to effectively form the opposing electrode across the indented tissue layer to be reshaped. The tissue will tend to permanently bend to conform to the **molded electrode**. (emphasis added)

There is nothing in Eggers which discloses a molded electrode surface which mechanically applies a force to the tissue to create external stresses applied to the tissue to temporally define and maintain a predetermined molded shape of the tissue as set out in amended claim 37.

Claim 49 is similarly distinguished from Eggers on the same grounds as amended claim 35 above, which grounds are here reinstated.

With respect to claim 50 the Examiner contends that Eggers discloses a means for applying a voltage of predetermined polarity (power source 28, voltage source 98, electrodes 58) to obtain a predetermined bioeffect comprises means for applying a first sequence of voltage pulses of the same polarity and means for applying a second sequence of voltage pulses of the opposite polarity to form a complex DC pulse train (control of pulses disclosed in col. 8:19-33; element 30).

Eggers discloses turning the RF dielectric heating to manage the temperature profile in the tissue. There is no disclosure relating applying voltages having single polarities and applying them in alternating polarity sequences to form a complex DC pulse train as required by claim 50. Eggers is inoperable or incapable of applying an RF pulse of a specific polarity since RF pulses have no polarities, being high frequency alternating waveforms. Being simply turned on and off as Eggers discloses is clearly not the same as being turned on in different sequences of different polarities.

With respect to clam 51 the Examiner contends that Eggers discloses the means for applying a first sequence and means for applying a second sequence of voltage pulses provide a net charge cancellation when integrated over an application time (control of pulses disclosed in col. 8:19-33; element 30).

Eggers is utterly silent in regard to the generation or application of a sequences of pulses which provide a net charge cancellation when integrated over an application time.

With respect to claim 52 the Examiner contends that Eggers discloses the means for flowing direct current from a positive electrode to obtain tissue compression in the proximity of the positive electrode. The Examiner contends that Eggers inherently discloses tissue compression at the positive electrode and need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

Eggers fails to disclose direct current flowing from a positive electrode into adjacent tissue in the context of an apparatus for electroforming. Therefore, Eggers fails to have the inherent teaching that is incorrectly attributed to it.

With respect to claim 53 the Examiner contends that Eggers discloses the means for flowing direct current from a negative electrode to obtain tissue lengthening in the proximity of the negative electrode as inherently disclosed at the negative electrode, and hence it need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

Again Eggers fails to disclose direct current flowing from a negative electrode into adjacent tissue in the context of an apparatus for electroforming. Therefore, Eggers fails to have the inherent teaching that is incorrectly attributed to it.

With respect to claim 54 the Examiner contends that Eggers discloses the means for creating tension, compression, shear or combinations thereof in the tissue. (col. 6:61-67). The Examiner contends that Eggers inherently includes tissue lengthening at the negative electrode and need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

Again since Eggers fails to disclose direct current flowing from a negative or positive electrode into adjacent tissue in the context of an apparatus for electroforming, , Eggers fails to have the inherent teaching that is incorrectly attributed to it.

With respect to claim 55 the Examiner contends that Eggers discloses the means for applying a DC voltage (power source 28, voltage source 98) for a predetermined application time across two paired conductive elements (electrodes 58) in contact with the tissue.

Claim 55 is distinguished from Eggers on similar grounds to claim 35, which grounds are here reinstated.

With respect to claim 56 the Examiner contends that Eggers discloses the means (10) for placing a solid conductive element (electrodes 58) in contact with the tissue, including solid conductive elements composed of metals or conductive polymers (col. 13:64-67).

Eggers discloses that electrodes 58 may be made of various types of metal, but never discloses that conductive polymer is used as the solid conductive element in the claimed context.

Rejection Pursuant to 35 USC 103

Claims 40, 46 and 47 are rejected as being obvious over Eggers in view of Balbierz.

The Examiner admits that Eggers is silent concerning the monitoring of stresses. The Examiner cites Balbierz as disclosing an analogous arrayed (Balbierz claim 34) electrode catheter with feedback control. The Examiner contends that Balbierz renders:

1. with respect to claim 40 the inclusion of a means for comprising monitoring (324 in figure 27; see col. 18:7-27) the stresses in the tissue and a means for controlling (338 in figure 27, 350,329,346) the current flowing in the tissue according to the stresses therein obvious in Eggers.
2. with respect to claim 46 the inclusion of a means for monitoring color of the tissue as caused by a chemical dye (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) disposed therein obvious in Eggers.

3. with respect to claim 47 the inclusion of a means for monitoring color (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) of the tissue as caused by electroplating a material thereon obvious in Eggers.

The Examiner cites Balbierz at col. 22:44-60:

> "Referring now to FIGS. 27 and 28, a feedback control system 329 can be connected to energy source 320, sensors 324 and energy delivery devices 314 and 316. Feedback control system 329 receives temperature or impedance data from sensors 324 and the amount of electromagnetic energy received by energy delivery devices 314 and 316 is modified from an initial setting of ablation energy output, ablation time, temperature, and current density (the "Four Parameters"). Feedback control system 329 can automatically change any of the Four Parameters. Feedback control system 329 can detect impedance or temperature and change any of the Four Parameters. Feedback control system 329 can include a multiplexer to multiplex different antennas, a temperature detection circuit that provides a control signal representative of temperature or impedance detected at one or more sensors 324. A microprocessor can be connected to the temperature control circuit."

The Examiner cites Balbierz (col. 18:7-27), for showing types of sensors including those making obvious the Applicant's claims (implicitly used in a feedback control configuration):

> "Sensor 22 can be of conventional design, including but not limited to thermal sensors, acoustical sensors, optical sensors, pH sensors, gas sensors, flow sensors positional sensors and pressure/force sensors. Thermal sensors can include thermistors, thermocouples, resistive wires, optical sensors and the like. A suitable thermal sensor 22 includes a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. Acoustical sensors can include ultrasound sensors including piezoelectric sensors which can be configured in an array. Pressure and force sensors can include strain gauge sensors including silicon based strain gauges. Optical sensors can include photomultipliers and micro-machined optical fibers. Gas sensors can include 0_2 sensors such as Clark electrodes, $C0_2$ sensors and other electrochemical based sensors known in the art. Flow velocity sensors can include ultrasound sensors, electromagnetic sensors and aneometric sensors which can be configured to detect both liquid and gaseous flows. Positional sensors can include LVDT's, and Hall effect sensors. Other sensors which can be employed impedance sensors, antibody-based sensors,

> biosensors (e.g. glucose) and chemical sensors. In various embodiments one sensor can be configured to detect multiple parameters or one or more sensors can be coupled together."

The Examiner then contends that it would have been obvious to modify Eggers in view of Balbierz by including the monitoring of stress in the targeted tissue as an alternate to Eggers' temperature feedback control as implied from Balbierz' alternate to temperature feedback control (e.g. impedance feedback control).

The Examiner combines Eggers with Balbierz to contend that those claims directed to monitoring stresses in the cartilage is rendered obvious by Balbierz' feedback of temperature or impedance data for delivery of energy. Balbierz never mentions stress in any context, it does not logical follow that providing feedback based on temperature or impedance with respect to parameters other than stress renders feedback control based on stress measurements as obvious. Neither Eggers nor Balbierz are concerned with modification of the stresses in tissues or in cartilage as a factor or mechanism for the reshaping of tissues or cartilage. Both Eggers and Balbierz use RF dielectric heating to ablate or cut tissue. In taking tissue away, both Eggers[1]

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[1] Eggers is directed to creating and controlling only tissue **necrosis**, where he states:

"The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue **necrosis** without substantially reducing power delivery and ablation rates. Heretofore, increased power delivery with electrosurgical devices has generally been achieved by increasing monolithic electrode area. The resulting large electrode surfaces, however, cause tissue **necrosis** to a depth which varies proportionally with the width and area of the electrode surface. The present invention provides a more controlled **necrosis** depth by utilizing a plurality of isolated electrode terminals, where the terminals are preferably laterally spaced-apart by a distance from one-tenth to one terminal diameter, with spacing between larger electrode terminals generally being at the lower end of the range. Such spacing provides adequate power delivery and ablation rates without excessive tissue **necrosis**, which is usually limited to a depth less than one electrode terminal diameter. Col. 3:35-52.

By contacting the electrode array(s) on the contact surface(s) against target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of **necrosis** to surrounding tissue. Col. 6:54 - 61.

"The use of small electrode terminals reduces the extent and depth of tissue **necrosis** as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., **necrosis**) has been found to be limited to a distance of about one-half to one electrode terminal diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue **necrosis** may not be sufficiently limited. " Col. 8:1 – 9.

"Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing depth of **necrosis** by providing multiple small electrode terminals." Col. 8:13 - 15.

The depth of **necrosis** may be further controlled by switching the applied voltage off and on to produce pulses of current, said pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. Col. 8:19 – 24.

Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and **necrosis** of the structure at the point of contact. Col. 11: 53 – 56.

Still referring to FIG. 3, another aspect of the present invention is the restriction of high current densities or fluxes to a confined region 62 as defined by the current flux lines 60. The confinement of the high current densities to a limited region 62 allows healthy tissue nearby to remain at or near normal physiologic temperatures, thereby limiting the depth of **necrosis** into surrounding or underlying healthy tissue 52 to a depth of approximately one electrode diameter. Alternatively, by energizing only one or several electrode terminals 58 at any one time, the depth of **necrosis** can be still further reduced since the thermal relaxation time between energy pulses for any specific electrode will serve to further limit the depth of **necrosis**. Col.12:60 – col. 13. 5.

The characteristic dimension D_1 (i.e., diameter in the case of circular electrodes shown in FIG. 6) ranges from 0.1 mm to 0.5 mm depending on the overall size of the probe, the rate of ablation required and the maximum allowed depth of **necrosis** of the body structure being treated. Col. 14:13 – 18.

Referring to FIG. 7 another embodiment of the present invention intended for smoothing of body structures (e.g., articular cartilage located on the surface of a condyle) while minimizing the depth of **necrosis** of the underlying tissue includes electrode terminals 58 in an electrical insulating matrix 48 is similar to the array shown in FIGS. 5 and 6 except that the electrode terminals 58 are flush with the surface of the electrically insulating matrix 48. The rate of ablation achievable with the use of "flush" electrode terminals 58 is lower than that for electrodes which extend beyond the face of the electrically insulative matrix 48, but such flush electrode structure can provide a

and Balbierz[2] change the net shape of the tissue, but they do not electroform the tissue to reshape it, i.e. to deform the tissue into a different shape without tissue excision or without necrosis or ablation. In other words, the modality by which the tissue shape is

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smoother surface on the body structure being treated while minimizing the depth of ablation and **necrosis**. Col. 14:35 – 48.

[2] Balbierz is also clearly concerned only with the control and extent of cell or tissue **necrosis** where he states:

"Still further, the invention provides the advantage of using minimally invasive methods to treat a selected pulmonary tissue volume to achieve a desired treatment endpoint including complete ablation/**necrosis** of the selected tissue with minimal effect on surrounding tissue." Col. 6, 19 – 25.

"The deployable electrodes 18 are configurable to allow volumetric cell **necrosis** to proceed from the interior, exterior of tissue site 5' as well as various combinations thereof in order to create a selectable and predictable cell **necrosis**." Col. 16: 43 – 47.

"Electrodes 18 and 18' can be selectably deployable from introducer 12 or deployable member 35 with curvature to create any desired geometric area of cell **necrosis**. The selectable deployment is achieved by having electrodes 18 with, (i) different advancement lengths from introducer 12, (ii) different deployed geometric configurations, (iii) variations in cross-sectional geometries, (iv) selectable insulation provided at each and/or all of the deployed electrodes 18, or (v) the use of adjustable insulation. Deployed electrodes 18 and/or 18' can create a variety of different geometric cell **necrosis** zones including but not limited to spherical, semi-spherical, spheroid, triangular, semi-triangular, square, semi-square, rectangular, semi-rectangular, conical, semi-conical, quadrilateral, semi-quadrilateral, rhomboidal, semi-rhomboidal, trapezoidal, semi-trapezoidal, combinations of the preceding, geometries with non-planar sections or sides, free-form and the like." Col. 17:7-23.

Turning to a discussion of sensors, the use of one or more sensors 22 coupled to the introducer, energy delivery devices, deployable member and biopsy needles and permits accurate measurement of temperature at tissue site 5' in order to determine, (i) the extent of cell **necrosis**, (ii) the amount of cell **necrosis**, (iii) whether or not further cell **necrosis** is needed and (iv) the boundary or periphery of the ablated tissue mass. Further, sensor 22 reduces non-targeted tissue from being injured, destroyed or ablated. Referring to FIG. 20, multiple sensors can be coupled to electrodes 18. Col. 17:51-60.

By monitoring the temperature at various points within and outside of the interior of tissue site 5', a determination of the selected tissue mass periphery can be made, as well as a determination of when cell **necrosis** is complete. Col. 17:65 – col.18:1.

In a similar manner, temperatures detected at sensors 324 provide feedback for determining the extent and rate of (i) tissue hyperthermia (ii) cell **necrosis**; and (iii) when a boundary of desired cell **necrosis** has reached the physical location of sensors 324. Col. 25:27-31.

mediated is not only based on a different bioeffect but performed in an entirely different way. Tissue stress has nothing to do with the success or failure of necrosis or ablation in Eggers and Balbierz. The fact that temperature, which is relevant to necrosis was monitored in Eggers and Balbierz is totally irrelevant to monitoring of tissue stresses in the present application, and does not constitute a reason for doing so.

Applicant respectfully requests advancement of the claims to allowance.

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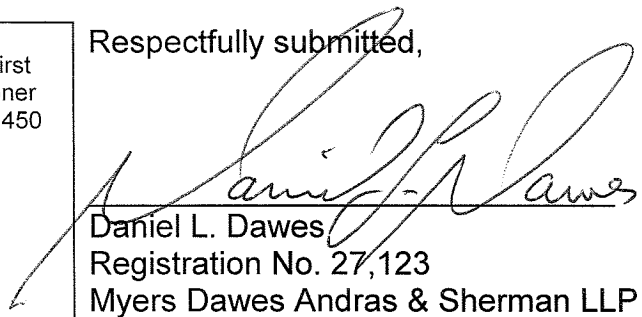
Respectfully submitted,



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